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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,885	05/02/2001	Robert Nakayama	18564-005910	5809
22428 7590 07/02/2007 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER TALBOT, BRIAN K'	
			ART UNIT 1762	PAPER NUMBER
			MAIL DATE 07/02/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/847,885

Applicant(s)

NAKAYAMA ET AL.

Examiner

Brian K. Talbot

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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1. The amendment filed 4/5/07 has been considered and entered. Claim 13 has been canceled. Claims 23-25 have been added. Claims 1-12 and 14-25 remain in the application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

3. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 depends upon a canceled claim (13). Clarification is requested.

***Claim Rejections - 35 USC § 103***

4. Claims 1-6, 9, 10 and 14-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. (5,571,401) or Lewis et al. (6,290,911) in combination with Hamamoto et al. (5,720,862), Yamamoto et al. (5,658,443), Say et al. (6,103,033) or Van Antwerp et al. (6,784,274) further in combination with JP 08-254,520.

Lewis et al. (5,571,401) or Lewis et al. (6,290,911) both teach sensor arrays for detecting analyte fluids. A sensing material comprising conducting and non-conducting material is blended to form the desired sensor. The sensing material is applied over a substrate having gold

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electrical contacts. The sensing material absorbs the detected material thereby providing a detectable response. The conductive material includes carbon black and the non-conducting polymers include a wide variety and can be applied by a variety of deposition processes including spraying and dipping. Arrays of sensors can be manufactured by these processes. The sensing material is applied by a variety of processes including spraying (abstract and col. 5, line 1 – col. 10, line 60).

Lewis et al. (5,571,401) or Lewis et al. (6,290,911) fail to teach coating a first conductive layer and then a non-conductive layer instead of a blended composition.

Hamamoto et al. (5,720,862) or Yamamoto et al. (5,658,443) both teach multilayered sensors having cover layers atop the sensing layer (Figure 1 in both references). Hamamoto et al. (5,720,862) teaches apertures in the top cover layer to allow the sample applied atop the cover layer to pass and penetrate toward the reactive layer and the electrode system. The layers are applied and dried (col. 8, lines 5-55). Yamamoto et al. (5,658,443) teaches that the top layer (8) allows infusion of the sample solution from the surface into the reaction layer. The layers are applied and dried (col. 6, line 35 – col. 7, line 20).

Say et al. (6,103,033) teaches a process for producing electrochemical biosensors. The sensor includes electrodes, a sensing layer and a microporous barrier film that allows diffusion of the analyte into the sensing film to make contact with the electrodes (col. 6, line 25 - col. 15, line 40).

Van Antwerp et al. (6,784,274) teaches a hydrophilic coating for biosensors. The sensor is comprised of an electrode covered by a sensing layer that is covered by a hydrophilic layer

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that improves diffusion of the analyte to the sensing layer/electrodes (col. 6, lines 20-60 and Figs. 10A and 10B).

Therefore it would have been obvious for one skilled in the art at the time the invention was made to have modified Lewis et al. (5,571,401) or Lewis et al. (6,290,911) sensor manufacturing process by coating individual layers as evidenced by Hamamoto et al. (5,720,862), Yamamoto et al. (5,658,443), Say et al. (6,103,033) or Van Antwerp et al. (6,784,274) with the expectation of achieving the desired results.

Lewis et al. (5,571,401) or Lewis et al. (6,290,911) in combination with Hamamoto et al. (5,720,862), Yamamoto et al. (5,658,443), Say et al. (6,103,033) or Van Antwerp et al. (6,784,274) fail to teach the post treatment of sensing film by exposing to a polar or non-polar substance, i.e. in a solvent.

JP 08-254,520 teaches a chemical censor composed of electrodes and a sensing film whereby the sensing film is left under a solvent atmosphere that can dissolve or swell the film or by heat treating (abstract).

Therefore it would have been obvious for one skilled in the art at the time the invention was made to have modified Lewis et al. (5,571,401) or Lewis et al. (6,290,911) in combination with Hamamoto et al. (5,720,862), Yamamoto et al. (5,658,443), Say et al. (6,103,033) or Van Antwerp et al. (6,784,274) process by incorporating a heat treatment in a solvent atmosphere as evidenced by JP 08-254,520 with the expectation of achieving similar results, i.e. swelling of the sensing film.

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With respect to claims 9 and 10 which recite the use of a robotic amateur. It has been well settled that the provision of mechanical or automated means to replace manual activity is held to have been an obvious modification of the art. *In re Venner 120 USPQ 192*

Claims 7,8,11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. (5,571,401) or Lewis et al. (6,290,911) in combination with Hamamoto et al. (5,720,862), Yamamoto et al. (5,658,443), Say et al. (6,103,033) or Van Antwerp et al. (6,784,274) further in combination with JP 08-254,520 still further in combination with De Witt et al. (6,572,826).

Features described above concerning Lewis et al. (5,571,401) or Lewis et al. (6,290,911) in combination with Hamamoto et al. (5,720,862), Yamamoto et al. (5,658,443), Say et al. (6,103,033) or Van Antwerp et al. (6,784,274) in combination with JP 08-254,520 are incorporated here.

Lewis et al. (5,571,401) or Lewis et al. (6,290,911) in combination with Hamamoto et al. (5,720,862), Yamamoto et al. (5,658,443), Say et al. (6,103,033) or Van Antwerp et al. (6,784,274) in combination with JP 08-254,520 fails to teach using a mask to apply the films.

De Witt et al. (6,572,826) teaches a chemically sensitive sensor whereby the sensing material can be applied by spraying with the use of a mask to applying the coating to specific areas of the substrate (col. 8, lines 25-40).

Therefore it would have been obvious for one skilled in the art at the time the invention was made to have modified Lewis et al. (5,571,401) or Lewis et al. (6,290,911) in combination with Hamamoto et al. (5,720,862), Yamamoto et al. (5,658,443), Say et al. (6,103,033) or Van

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Antwerp et al. (6,784,274) in combination with JP 08-254,520 multi-layered sensor by applying the layers with a masking means as evidenced by De Witt et al. (6,572,826) with the expectation of achieving a more precise and accurate deposition pattern.

### ***Response to Arguments***

5. Applicant's arguments with respect to claims 1-12 and 14-25 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argued that the prior failed to teach the post processing of the applied films in a solvent atmosphere, i.e. solvating.

JP 08-254,520 teaches this limitation as noted above. In addition, Say et al. (6,103,033) teaches solvating a sensing material (col. 15, lines 25-42).

Regarding claims 15 and 23 reciting the “design” of the sensor array, it is the Examiner’s position that this would be a matter of design choice by a practitioner in the art and absent a showing of criticality regarding such designs would be deemed as an obvious modification of the prior art. It is noted that Applicant stated that they are an advancement over the prior art and not mere design choices, however, no such “advancements” were detailed as to what they are and how they are affected by the design.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian K. Talbot whose telephone number is (571) 272-1428. The examiner can normally be reached on Monday-Friday 6AM-3PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy H. Meeks can be reached on (571) 272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brian K Talbot  
Primary Examiner  
Art Unit 1762

BKT